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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 18

### Complete if Known

Application Number	09/625,384
Filing Date	July 26, 2000
First Named Inventor	Richard A. Mueller et al.
Group Art Unit	1625
Examiner Name	B. Robinson
Attorney Docket Number	001765.00054 (C-3128/1)

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
BMA		US-4,146,645	03/79	Schromm et al.	
		US-4,252,804	02/81	Joulli et al.	
		US-4,268,688	05/81	Tinker et al.	
		US-4,344,949	08/82	Hoefle et al.	
		US-4,450,164	05/84	Bristol	
		US-4,477,441	10/84	Boger et al.	
		US-4,514,391	04/85	Gordon et al.	
		US-4,548,926	10/85	Matsueda et al.	
		US-4,595,407	06/86	Carter	
		US-4,599,198	07/86	Hoover	
		US-4,616,088	10/86	Ryono et al.	
		US-4,629,724	12/86	Ryono et al.	
		US-4,634,465	01/87	Ehrenfreund et al.	
		US-4,644,055	02/87	Kettner et al.	
		US-4,652,552	03/87	Kettner et al.	
		US-4,668,769	05/87	Hoover	
		US-4,668,770	05/87	Boger et al.	
		US-4,703,037	10/87	Huang et al.	
		US-4,757,050	07/88	Natarajan et al.	
		US-4,783,776	11/88	Ishigaki et al.	
		US-4,826,815	05/89	Luly et al.	
		US-4,857,507	08/89	Rosenberg et al.	
		US-4,857,511	08/89	Rideout et al.	
		US-4,880,938	11/89	Freidinger	
		US-4,908,386	03/90	Finch et al.	
		US-4,963,530	10/90	Hemmi et al.	
		US-4,977,277	12/90	Rosenberg et al.	
		US-4,990,669	02/91	Reetz et al.	
		US-5,122,514	06/92	Boger et al.	
		US-5,122,517	06/92	Vince et al.	
		US-5,128,346	07/92	Nadzan et al.	
		US-5,132,400	07/92	Gammill et al.	
		US-5,134,123	07/92	Branca et al.	
		US-5,140,011	08/92	Branca et al.	

Examiner  
Signature

*B. Robinson*

Date  
Considered

1/5/02

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet 2 Of 18

**Complete if Known**

Application Number	09/625,384
Filing Date	July 26, 2000
First Named Inventor	Richard A. Mueller et al.
Group Art Unit	1625
Examiner Name	B. Robinson
Attorney Docket Number	001765.00054 (C-3128/1)

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
<i>B. Robinson</i>		US-5,151,438	09/92	Sham et al.	
		US-5,157,041	10/92	Handa et al.	
		US-5,194,609	03/93	Saroca et al.	
		US-5,256,783	10/93	Gokhale et al.	
		US-5,278,148	01/94	Branca et al.	
		US-5,340,828	08/94	Graham et al.	
		US-5,387,512	02/95	Balani et al.	
		US-5,413,999	05/95	Vacca et al.	
		US-5,458,889	10/95	Bourbon et al.	
		US-5,463,104	10/95	Vazquez et al.	
		US-5,475,013	12/95	Talley et al.	
		US-5,475,027	12/95	Talley et al.	
		US-5,476,874	12/95	Hungate et al.	
		US-5,482,947	01/96	Talley et al.	
		US-5,484,926	01/96	Dressman et al.	
		US-5,504,104	04/96	Eisworth et al.	
		US-5,508,294	04/96	Vazquez et al.	
		US-5,510,349	04/96	Talley et al.	
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		US-5,510,388	04/96	Vazquez et al.	
		US-5,510,487	04/96	Talley et al.	
		US-5,514,801	05/96	Bertenshaw et al.	
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		US-5,578,606	11/96	Vazquez et al.	
		US-5,583,132	12/96	Vazquez et al.	
		US-5,585,397	12/96	Tung et al.	
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		US-5,602,175	02/97	Talley et al.	
		US-5,610,190	03/97	Talley et al.	
		US-5,614,522	03/97	Talley et al.	
<i>B. Robinson</i>		US-5,620,977	04/97	Talley et al.	

Examiner  
Signature*Binta Robinson*Date  
Considered*1/5/03*

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Substitute for form 1449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	09/625,384	
			Filing Date	July 26, 2000	
			First Named Inventor	Richard A. Mueller et al.	
			Group Art Unit	1625	
			Examiner Name	B. Robinson	
Sheet	3	of	18	Attorney Docket Number	001765.00054 (C-3128/1)

U.S. PATENT DOCUMENTS					
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BMR		US-5,622,949	04/97	Talley et al.	
		US-5,639,769	06/97	Vazquez et al.	
		US-5,643,924	07/97	Talley et al.	
		US-5,648,364	07/97	Talley et al.	
		US-5,698,569	12/97	Talley et al.	
		US-5,703,076	12/97	Talley et al.	
		US-5,705,500	01/98	Getman et al.	
		US-5,708,004	01/98	Talley et al.	
		US-5,714,605	02/98	Vazquez et al.	
		US-5,723,490	03/98	Tung et al.	
		US-5,744,481	04/98	Vazquez et al.	
		US-5,750,648	05/98	Chang et al.	
		US-5,753,660	05/98	Sikorski et al.	
		US-5,756,498	05/98	Vazquez et al.	
		US-5,756,533	05/98	Getman et al.	
		US-5,756,534	05/98	Talley et al.	
		US-5,760,064	06/98	Vazquez et al.	
		US-5,760,076	06/98	Vazquez et al.	
		US-5,776,971	07/98	Getman et al.	
		US-5,786,483	07/98	Vazquez et al.	
		US-5,830,888	11/98	Getman et al.	
		US-5,830,897	11/98	Vazquez et al.	
		US-5,843,946	12/98	Vazquez et al.	
		US-5,849,784	12/98	Bertenshaw et al.	
		US-5,856,353	01/99	Tung et al.	
		US-5,948,790	09/99	Talley et al.	
		US-5,965,601	10/99	Getman et al.	
		US-5,965,588	10/99	Vazquez et al.	
		US-5,968,942	10/99	Vazquez et al.	
		US-5,968,970	10/99	Getman et al.	
		US-5,972,989	10/99	Getman et al.	
		US-5,977,137	11/99	Tung et al.	
		US-5,985,870	11/99	Getman et al.	

Examiner Signature		Date Considered	1/5/03
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**Complete if Known**

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Sheet	4	of	18
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Application Number	09/625,384
Filing Date	July 26, 2000
First Named Inventor	Richard A. Mueller et al.
Group Art Unit	1625
Examiner Name	B. Robinson
Attorney Docket Number	001765.00054 (C-3128/1)

[illegible]

**Examiner  
Signature**

Bento Robinson

Date Considered

11/5/03

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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 18

## Complete if Known

Application Number	09/743,460
Filing Date	August 20, 2001
First Named Inventor	Richard A. Mueller et al.
Group Art Unit	1625
Examiner Name	Z. Davis
Attorney Docket Number	001765.00054 (C-3128/1)

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		AU A-79823/87 (Abstract Only)	04/88			
		EP 0104041 A1	03/84			
		EP 0114993 A2	08/84			
		EP 0172347 A2	02/96			
		EP 0223437 A2	05/87			
		EP 0264795 A2	04/88			
		EP 0264795 A3	04/88			
		EP 0337714 A2	10/89			
		EP 0342541 A2	11/89			
		EP 0346847 A2	12/89			
		EP 0356223 A2	02/90			
		EP 0364804 A1	04/90			
		EP 0389898 A2	10/90			
		EP 0389898 A3	10/90			
		EP 0393445 A2	10/90			
		EP 0393457 A1	10/90			
		EP 0402646 A1	12/90			
		EP 0468641 A2	01/92			
		EP 0468641 A3	01/92			
		EP 0480624 A1	04/92			
		EP 0480711 A1	10/91			
		EP 0480714 A2	10/91			
		EP 0541168 A1	05/93			
		EP 0580402 A2	07/93			
		EP 0617968 A1	10/94			
		EP 0691345 A2	01/96			
		EP 0691345 A3	02/99			
		GB 2184730 A	07/87			
		GB 2200115 A	07/88			

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Sheet 6 of 18

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Filing Date	July 26, 2000
First Named Inventor	Richard A. Mueller et al.
Group Art Unit	1625
Examiner Name	B. Robinson
Attorney Docket Number	001765.00054 (C-3128/1)

**FOREIGN PATENT DOCUMENTS**

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		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		GB 2209752	05/89			
		WO 84/03044	08/84			
		WO 92/08688	05/92			
		WO 92/08699	05/92			
		WO 92/08701	05/92			
		WO 92/14703	09/92			
		WO 93/09096	05/93			
		WO 93/13066	07/93			
		WO 93/23368	11/93			
		WO 93/23379	11/93			
		WO 94/04491	03/94			
		WO 94/04492	03/94			
		WO 94/04493	03/94			
		WO 94/05639	03/94			
		WO 94/08458	04/94			
		WO 94/10133	05/94			
		WO 94/10134	05/94			
		WO 94/10136	05/94			
		WO 95/07696	03/95			
		WO 96/00068	01/96			
		WO 96/04913	02/96			
		WO 96/22287	07/96			
		WO 96/28418	09/96			
		WO 97/01349	01/97			
		WO 99/33792	04/99			
		WO95/06030	03/95			
		WOA95/33464	12/95			

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**INFORMATION DISCLOSURE  
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Sheet 7 of 18

**Complete if Known**

Application Number	09/625,384
Filing Date	July 26, 2000
First Named Inventor	Richard A. Mueller et al.
Group Art Unit	1625
Examiner Name	B. Robinson
Attorney Docket Number	001765.00054 (C-3128/1)

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BUTTERWORTHS, "Handbook of Reactive Chemical Hazards", 3rd Ed., 1985, p. 295	
		A. BURGER, Med. Chem., 2nd Ed., 1960, pp. 565-601	
		Abstract No. 199, "Salvage Therapy Using the Combination of Zidovudine and Zalcitabine in Patients with Advanced HIV Infection," 4th Conf Retro and Opportun Infect, Jan. 22-26, 1997, p. 101	
		Abstract No. 209, "Selection and Analysis of HIV-1 Variants With Increased Resistance to AZT-3TC, A Novel Protease Inhibitor," 4th Conf Retro and Opportun Infect, Jan. 22-26, 1997, p. 103	
		Abstract No. 245, "Efficacy and safety of Quadruple Combination Therapy in Treatment Experienced HIV/AIDS Patient," 4th Conf Retro and Opportun Infect, Jan. 22-26, 1997, p. 103	
		Abstract No. 257, "The Use of Antiretroviral Therapy in Association With Evolving Standards of Practice," 4th Conf Retro and Opportun Infect, Jan. 22-26, 1997, p. 111	
		Abstract No. 609, "Pharmacokinetics/pharmacodynamics of Zidovudine-Zalcitabine Combination Therapy," 4th Conf Retro and Opportun Infect, Jan. 22-26, 1997, p. 177	
		Abstract No. Th.B. 934, "Combination Use of Zidovudine and Zalcitabine in HIV-Infected Patients: Preliminary Safety and Activity Data," Int Conf Aids (United States), Jul. 7-12, 1996 (Program Supplement, p. 20)	
		Abstract, "Zidovudine," Bioorganic and Medicinal Chemistry, 5/3, pp. 461-462, 1997	

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		Filing Date	July 26, 2000
		First Named Inventor	Richard A. Mueller et al.
		Group Art Unit	1625
		Examiner Name	B. Robinson
Sheet 8 of 18	Attorney Docket Number	001765.00054 (C-3128/1)	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		Abstract, "Saquinavir Pharmacokinetics Alone and in Combination With Zidovudine in HIV-Infected Patients," United Kingdom, AIDS, 11/4 (F29-F33), 1997	
		Abstract, "Protease Inhibitors in Patients With HIV Disease. Clinically Important Pharmacokinetic Considerations," Clinical Pharmacokinetics, 1977, 32/3 (194-209)	
		ANDERSON, Design of Prodrugs, edited by Hans Bungaard (Elsevier, Amsterdam), 1985, p. 244	
		BARRY et al, "Protease Inhibitors in Patients with HIV Disease Clinically Important Pharmacokinetic Consideration," Pharmacokinetic-Pharmacodynamic Relationships, pp. 194-209, 1997	
		BECKER, International Dictionary of Medicine and Biology, 1986, p. 2316	
		BOLIS et al, J. Med. Chem., 30, 1987, pp. 1729-37	
		BUNGAARD, Drugs of the Future, 16 (5), 1991, p. 443-458	
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# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

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Sheet 9 Of 18

## **Complete if Known**

Application Number	09/625,384
Filing Date	July 26, 2000
First Named Inventor	Richard A. Mueller et al.
Group Art Unit	1625
Examiner Name	B. Robinson
Attorney Docket Number	001765.00054 (C-3128/1)

## **OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		COLE et al, "An Improved Method for the Synthesis of 2,2-Disubstituted and 2-Monosubstituted 1,3-Benzodioxoles", Department of Applied Organic Chemistry	
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		Filing Date	July 26, 2000
		First Named Inventor	Richard A. Mueller et al.
		Group Art Unit	1625
		Examiner Name	B. Robinson
Sheet 10 of 18	Attorney Docket Number	001765.00054 (C-3128/1)	

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		ERICKSON et al, "Design Activity, and 2.8 Å Crystal Structure of a C <sub>2</sub> Symmetric Inhibitor Complexed to HIV-1 Protease, Science, Vol. 249, August 1990, pp. 527-533	
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				First Named Inventor	Richard A. Mueller et al.
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(use as many sheets as necessary)				Attorney Docket Number	001765.00054 (C-3128/1)
Sheet	11	of	18		

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		HARGRAVE, J. Med. Chem., 34, 1991, pp. 2231-2241	
		HIRSCH et al, "Therapy for Human Immunodeficiency Virus Infection", New England Journal of Medicine, vol. 328	
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		J. Med. Chem., 34:2692-2701, 1991	
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 13 of 18

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		LAURENCE, J. et al, The Lancet, 1 Aug. 1992, vol. 340, pp. 273-274	
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			First Named Inventor	Richard A. Mueller et al.	
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Sheet	14	of	18	Attorney Docket Number	001765.00054 (C-3128/1)

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		MILLER et al, Science, 246, 1989, p. 1149	
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				Filing Date	July 26, 2000
				First Named Inventor	Richard A. Mueller et al.
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Sheet	15	of	18	Attorney Docket Number	001765.00054 (C-3128/1)

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		Pure Appl. Chem., 45, 13-30 (1976).	
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Sheet 16 of 18

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		S. H. YALKOWSKY, "Drugs and the Pharmaceutical Sciences: Techniques of Solubilization of Drugs", Marcel, Drugs and the Pharmaceutical Science, Vol. 12, 1981	
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		TAM et al., "Intriguing Structure-Activity Relations Underlie the Potent Inhibition of HIV Protease by Norstatine Based Peptides", J. Med. Chem. 35:1318-1320 (1992).	
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<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO

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*(use as many sheets as necessary)*

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Application Number	09/625,384
Filing Date	July 26, 2000
First Named Inventor	Richard A. Mueller et al.
Group Art Unit	1625
Examiner Name	B. Robinson
Attorney Docket Number	001765.00054 (C-3128/1)

[illegible]

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Signature

Date  
Considered

<sup>1</sup> Unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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